

CLAIMS

We claim,

1. A process for a needle-free jet injection depositing a subcutaneous, intradermal or intramuscular injection of medicament into the tissue of a human or animal, from a disposable, single use, filled or pre-filled ampule, with the use of vacuum provided by an injector, that is manually or externally air pressurized for activating and sequencing said injector components,
 - (a) said process injects a premeasured dose of medicament, from said ampule, by means of a high pressure jet stream of sufficient velocity to penetrate the epidermis, depositing the medicament intradermally, subcutaneously or intramuscularly depending on the injector impact force and the offset of the ampule's orifice from the epidermis, and uses the vacuum to stretch the recipient's skin which increases its permeability for injection, positions it correctly for injection and reduces the amount of energy required to inject the medicament,
 - (b) said process injects said medicament horizontally to vertically, or other desired angle, into the skin, in a single use application, spreading the particles over a larger area than when using a needle syringe,
 - (c) said process provides decreased local pressure at point of injection during said injection process, reducing local pain, minimizing tissue damage, eliminating leakage of fluid at said injection opening and reducing the possibility of spreading infections while providing an interlock safety device to prevent inadvertent triggering of said injector.
2. An injector for said injection described in Claim 1, that is comprised of a housing that contains a piston to create said vacuum for stretching the recipient's skin on injection application and for the release mechanism that drives said medicament into the skin tissue,
 - (a) said housing of said injector comprising a compression drive spring that drives the

- drive rod into said ampule containing medicament, and said rod contains a retention ring used for locking said rod with said spring compressed, and a projecting ring for the spring to push against,
- (b) said housing contains a drive rod latch for capture of said rod with said spring compressed, and is preloaded to the release position by a torsion spring driven down to a locking position that captures said rod projecting ring, and said drive rod latch is driven down against said spring load with a spring ramp retained by two pins,
- (c) said drive rod latch is supported by a slide frame and can rotate in the upright supports of said frame, and retained with a horizontal pin that retains a connector link, and said slide frame has a horizontal lower leg that slides in a groove in said housing, and said horizontal leg contains an end termination for attachment of an extension link that can rotate,
- (d) said injector handle attached to the outside of said housing contains two contoured legs that straddle said housing, and each leg is attached to said pivot point in said housing, and said handle is shaped to provide finger or hand grips, and can rotate around said pivot that is retained by a capture pin,
- (e) said handle of extended length provides leverage for compressing said drive rod compression spring, containing said extension link that can rotate around said handle attachment point, and permits said link to rotate when said handle is rotated, and attached to said slide frame, it pivots about at the opposite end from said handle, so that when said handle is rotated down or up, said extension link pushes or pulls on said slide frame,
- (f) said slide frame movement in one direction pulls said drive rod to the latched position, with a connector link attached to the upright supports of said frame and on the opposite end is attached to a piston extension with a rod latch pivot pin,

- (g) said piston provides a vacuum for said injector when applied to the recipient's skin to pull the skin tight against suction ports in said ampule, and position said outlet orifice correctly for injection of medicament, and provides a vacuum seal to said ampule with the skin to prevent inadvertent triggering of said injector with the use of an interlock piston rod to engage or disengage said release catch,
- (h) said piston that contains an O-ring seal that ensures said piston can produce vacuum for actuation of said small interlock piston rod, and ensures said vacuum provided will position said interlock piston rod to engage said release arm, and either lock it in non-release, or release position, and said arm is torsion spring loaded to lock position and able to rotate to the two operating positions around a pivot pin that interfaces with said injector housing,
- (i) said release button installed in said injector housing that when pushed inward contacts said release arm and rotates it downward to lift said release catch that locks said compression spring in its compressed position, and said button is retained in said injector housing flush with the structure's outer surface to prevent operators from inadvertently pushing of said button down until required by the operating procedure and is retained in said structure with a retention snap ring,
- (j) said release catch contains said torsion spring that drives it into the lock position to hold said drive rod against said compression spring and contains an angular surface that provides for contact with said release arm during release function, and said release catch is pivoted around said pivot point provided by said latch pin that engages said housing,
- (k) a suction manifold system comprised of vacuum ports in said housing to receive vacuum pressure from said vacuum piston and conduct a vacuum through ported passages in said structure to said interlock piston chamber, and to said suction tubes that interface with said ampule, and said passages are sequentially

opened and closed by positioning of said interlock piston and a pair of suction tubes conduct suction to said suction ports, in said ampule.

3. Said injector of Claim 1 wherein is externally air pressurized for activating said vacuum and sequencing said injector components,
 - (a) said injector contains a trigger assembly operated by the operator's finger for initiation and movement of a valve in the said injector that opens and blocks externally supplied air pressure to a return piston that is connected to a vacuum piston with a connecting rod,
 - (b) said vacuum piston provides said vacuum for interlock functions of said release button and release catch to initiate injection of medicament, and said piston is moved by said return piston to create a vacuum at the interface contact surface of the recipient's skin and said ampule containing said medicament,
 - (c) a small compressing spring installed between said drive rod and said drive cylinder to ensure constant contact with said ampule plunger and prevent impact of said drive rod.
4. Said disposable filled ampule of Claim 1, attached to said injector and contacts vacuum tubes, that engage a chamber for containing medicament, having an internal seal that captures medicament inside said chamber,
 - (a) said ampule whose chamber is provided with gradient markers on the exterior surface to indicate the quantity of medicament within, and said chamber is contoured on its inner surface and contains a precision contoured throat to aid in acceleration of medicament injection by reduction of the fluid drag when said ampule receives an impact impulse from said spring loaded drive rod and increases the acceleration of said piston which results in a faster pressure rise and injection of medicament, and therefore, the medicament

is driven out of said ampule with a known controlled impact impulse force,

(b) said ampule contains said outlet orifice that is varied in location by varying the distance between the centerline of said orifice and the vacuum port plane, and can contain said intradermal, subcutaneous or intramuscular injection medicaments and horizontally inject them into predetermined depths in skin tissue layer, by controlling the dispersement of medicament, by varying the angle between the perpendicular to said orifice and the vacuum port level plane,

c) said ampule contains locking tabs on each end for engagement with said injector, in order to be correctly positioned and retained for engagement with said vacuum suction ports, and the interface surface is sealed with said suction ports, that engage recipient's skin and stretches the skin between said ports for medicament injection into the skin,

d) said ampule has provisions for filling with medicament from an external supply by either use of an adaptor assembly that holds and seals said ampule for filling medicament with a needle syringe through said injector's orifice, or filling through a stopper with provisions for insertion of a probe on a nozzle, that penetrates said stopper in said ampule, and whose said nozzle contains a shoulder that bears on said ampule's surface and automatically locates said probe correctly for medicament filling, after evacuating air from said ampule prior to filling of medicament and sealing of the passage evacuated, and then reinserting said probe on said nozzle through said stopper, and filling said ampule with medicament,

(e) a means for plugging of said ampule orifice with a plug, when filling medicament, and said plug contains an enlarged head for installation and removal, with a capture pad to prevent it from being sucked into said orifice and from being driven out of said orifice, with the use of a protective outer doubler covering and all other openings of said ampule are protected with coverings to maintain full sterile conditions within said ampule, and provide for removal and disposal of said ampule orifice plug with the disposed said protective shield that contains a tab for easier removal of said shields from said ampule.